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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,192	03/01/2002	David W. Morris	529452000122	7201

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EXAMINER	
HARRIS, ALANA M	
ART UNIT	PAPER NUMBER
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	03/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/087,192	MORRIS ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Applicants are required to elect one Invention listed below as Groups I-XI. Applicants indicate on page 41 of the specification that carcinoma associated (CA) nucleic acid sequences of the claims are depicted in Table 1 06-001 to 06-343, see line 33. With the election of one Invention or one Group, Applicants are required to identify the sequence for examination, noting the name of the mouse or human gene (from the lists found on pages 42-48 of the specification) or its encoded protein and its SEQ ID number. ***This is not a species election. Applicants are put on notice that the instant action is a restriction requirement and not a species election.*** If Applicants elect an Invention that reads on a nucleic acid Applicants will be afforded the search of the genomic sequence and its mRNA. Even though the numbers listed on the far left column of the lists on pages 42-48 correspond to both a mouse and human molecule Applicants must elect one of the two, mouse or human molecules.

Applicants are requested to ***select one sequence*** found within the voluminous sequence listing and Table.

If Applicants have any questions regarding this requirement they are encouraged to contact the Examiner for clarification in order to avoid a potential subsequent non-responsive letter.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to a recombinant nucleic acid listed in Table 1 consisting of sequences, 06-001 to 06-343 and the expression vector and

host cell, which the said nucleic acid is contained, respectively, classified in class 536, subclass 23.5.

II. Claim 5, drawn to a recombinant protein encoded by one of the sequences (06-001 to 06-343) listed in Table 1, respectively, classified in class 530, subclass 350.

III. Claims 6 and 7, drawn to a method of screening drug candidates comprising providing a cell that expresses a CA gene comprising a nucleic acid sequence (06-001 to 06-343) listed in Table 1 and adding a drug candidate to said cell and determining the level of CA gene expression, respectively, classified in class 435, subclass 6.

IV. Claims 8 and 9, drawn to a method of screening for a bioactive agent capable of binding and modulating the activity of an CA protein (CAP) encoded by one of the sequences identified as 06-001 to 06-343 comprising combining said CAP and a candidate bioactive agent and determining bioactivity of said CAP, respectively, classified in class 435, subclass 7.1.

V. Claims 10 and 11, drawn to a method of evaluating the effect of a candidate carcinoma drug comprising administering said drug to a patient, removing a cell sample and determining alterations in the expression or activation of a gene comprising a nucleic acid sequence (06-001 to 06-343) consisting of a sequence outlined in Table 1, respectively, classified in class 436, subclass 63.

VI. Claim 12, drawn to a method for inhibiting the activity of a CAP encoded by one of the nucleic acid sequences (06-001 to 06-343) outlined in Table 1, classified in class 435, subclass 7.1.

VII. Claims 13 and 14, drawn to a method of treating carcinomas comprising administering to a patient an inhibitor of an CAP, wherein the CAP is encoded by one of the nucleic acid sequences (06-001 to 06-343) outlined in Table 1, classified in class 424, subclass 130.1.

VIII. Claims 15 and 16, drawn to an antibody, which specifically binds to a protein encoded by one of the nucleic acid coding sequences (06-001 to 06-343) outlined in Table 1, classified in class 530, subclass 387.1.

IX. Claim 17, drawn to a biochip comprising one or more nucleic acid segments selected from the group consisting of one of the nucleic acid of the sequences (06-001 to 06-343) outlined in Table 1, respectively, classified in class 536, subclass 23.1.

X. Claim 18, drawn to a method of diagnosing carcinoma by sequencing one CA gene (06-001 to 06-343) in Table 1, classified in class 536, subclass 174.

XI. Claim 19, drawn to a method of determining CA gene copy number comprising adding a CA gene probe comprising a sequence (06-001 tp 06-343) of Table 1 to a sample of genomic DNA from an individual and implementing hybridization, classified in class 435, subclass 7.92.

3. The inventions are distinct, each from the other because of the following reasons:

Groups I, II, VIII and IX are structurally and functionally different products, which are made by different methods and have different uses. The recombinant nucleic acids of Group I are complex, high-molecular-weight biochemical macromolecule composed of nucleotide chains that convey genetic information. The most common nucleic acids are deoxyribonucleic acid (DNA) and ribonucleic acid (RNA). Group II, protein products are relatively large organic compounds made of amino acids arranged in a linear chain and joined together by peptide bonds between the carboxyl and amino groups of adjacent amino acid residues. The antibodies of Group VIII are large Y-shaped proteins that can bind to cancer cell-specific antigens and induce an immunological response against the target cancer cell. And the biochips of Group IX are essentially miniaturized laboratories that can perform hundreds or thousands of simultaneous biochemical reactions. Biochips enable researchers to quickly screen large numbers of biological analytes for a variety of purposes, from disease diagnosis to detection of bioterrorism agents.

The methods of Groups III-VII, X and XI differ in the method objectives, method steps and parameters and in the reagents used.

The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

Inventions III, IV, VI, X, XI and V, VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

different modes of operation, different functions, or different effects (MPEP э 806.04, MPEP э 808.01). In the instant case the *in vitro* methods of Inventions III, IV, VI, X and XI are distinct and independent from the *in vivo* methods of Inventions V and VII and are not useable or searchable together.

Invention IX is related to Groups III-V and XI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP э 806.05(h)). In the instant case, the biochip products of Group IX could be used in any of the methods of Group III-V and XI.

Inventions V, VII are unrelated to Invention IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP э 806.04, MPEP э 808.01). In the instant case, the methods Groups of V, VII cannot use the biochips of the Group IX, thus not useable nor searchable together.

4. 4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
12 March 2007